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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,686

07/28/2003

Gabriele Lualdi

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4591

7590

08/01/2006

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,686	LUALDI ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,7 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,15,16,18,25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,10,13,14,17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 4/6/06 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,7,13,17,21,22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tornier (5358526). Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Fig. 1 shows a prosthesis having a hemispherical head **3**, a flange-type insert **2** and pin means **1** with a greater section at an end coupled with the insert. Flange type insert is coupled to head by a first conical coupling **25** and coupled to the pin means by a second conical coupling **22**. Tornier discloses the couplings are conical, col. 3, lines 33,34,42. Tornier additionally discloses (col. 3, line 7) the pin means is a cylindrical rod **10**. It can be seen the coupling means are removable. Tornier discloses the flange-type insert is coupled

eccentrically with the head, col. 3, lines 45-50. Fig. 6 illustrates that flange-type insert would be able to be cemented on a top portion of bone via flange **24**.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,6,7,13,14,17,21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. (3064645) in view of Tornier '526. Fig. 1 shows a femoral prosthesis with "substantially cylindrical" pin means **1** with a conical shape and a smaller end and a larger end where it is coupled to the head. Fig. 9 shows a removable femoral head **11** and flange-type insert **8** that is capable of being inserted into a seating of the femoral head via the upward projections **17** forming a conical coupling. Figs. 5-7 illustrate that the coupling means **8** comprise a flange **10**. Fig. 8 illustrates that the coupling means **8** is connected to the pin means via threaded portion **9**. Fig. 13 shows flange-type insert capable of being cemented on the top portion of the femur. It can be construed that the flanged insert is coupled eccentrically with the femoral head. Ficat discloses inserting the stem or pin in the femur (Fig. 8) and then has the coupling means and head applied. It is inherent that the head is applied last since the apparatus is designed as removable and is implanted according to the patient's specifications or anatomical requirements, col. 2, lines 15-20. Ficat also shows (Fig. 13) a first portion or a mating cavity area that is capable of being coupled by a first coupling and the coupling being coaxial with the second coupling. However, Ficat et al. fail to disclose two conical couplings. Tornier shows (Fig. 1) two conical type couplings (**22,25**) to couple flange-

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type insert with head and stem. It would have been obvious to one of ordinary skill in the art to use two conical couplings as taught by Tornier with the prosthetic femoral device of Ficat such that it simplifies the joining of the components but provides a strong coupling. A modification in the coupling means to substitute a conical type coupling for the threaded coupling involves only routine skill in the art. Tornier teaches the coupling of the components is done by Morse taper (col. 3, lines 33-39,60-62) that is self-securing.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Tornier '526 as applied to claim 1 above, and further in view of Callaway et al. (6736852). Ficat et al. in view of Tornier is explained supra. However, Ficat et al. as modified by Tornier fail to disclose the upper part of the housing in the flanged insert clamped to the pin means by a screw. Callaway et al. teach (Fig. 3a) a prosthesis with a screw **20** to be placed in an upper zone of housing **22** of a flanged insert **18** on a seating **14** to clamp together with pin means **12**. It would have been obvious to one of ordinary skill in the art to modify the coupling of the components and incorporate a screw as taught by Callaway et al. in the prosthesis of Ficat et al. as modified by Tornier since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Claims 19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Tornier '526 as applied to claim 1 above, and further in view of Pappas et al. (5030234). Ficat et al. in view of Tornier is explained supra. Ficat does disclose the head is made of a cobalt alloy, col. 5, line 49. However, Ficat et al. as

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modified by Tornier fail to disclose the pin means and the flanged insert being made of titanium. Pappas et al. teach that stems made of titanium are more flexible than cobalt alloys, col. 6, lines 53-61. It would have been obvious to one of ordinary skill in the art to modify the pin means and insert to be of titanium as taught by Pappas et al. in the prosthesis of Ficat et al. as modified by Tornier since it will provide a more flexible stem to insert in the bone, but provides a strong articulating head.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

